K081560

FEB 10 2009

510(k) SUMMARY

VASCUTEK CANNULA GRAFT

Date prepared: 20th of May 2008
Revised: 10th February 2009

Common/Usual Name : Cardiopulmonary bypass vascular catheter, cannula, or tubing

Proprietary Name(s) : Vascutek Cannula Graft (Model Number: CGS2008S)

Classification Name : Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass

Classification : The Food and Drug Administration has classified these devices as Class II devices under classification 21 CFR 870.4210. Classification, DWF.

Applicant and : 510(k) submitter
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Device Predicates:

Predicate Device Name	Common Name	Classification	FDA Clearance Date	510(k)
Terumo Soft-Flow® Cannula	Cardiopulmonary bypass vascular catheter, cannula, or tubing	Class II DWF	22nd February 1994	K934127
Vascutek SEALPTFE Wrap graft	Vascular graft, prosthesis	Class II DSY	14th September 2004	K041528

Device Description:

The Vascutek Cannula Graft is a modified device design. It is a combination of a Terumo Soft-Flow® Aortic Cannula (K934127) and a Vascutek SEALPTFE Wrap graft (K041528). It is intended for use in perfusion during cardiopulmonary bypass procedures. The reason for the modification is summarised as follows. Direct introduction of a cannula tip into a patient's blood vessel may cause tissue trauma during attachment of the patient to a cardiopulmonary bypass machine. Replacement of the cannula tip with a softer,

SEALPTFE Wrap vascular graft, maybe less traumatic and be preferred by some surgeons. This is the design rationale for the Vascutek Cannula Graft.

There are no new materials used in the Vascutek Cannula Graft, other than the use of medical grade adhesive to create the bond between the Terumo Soft-Flow® Cannula (K934127) and Vascuteks SEALPTFE Wrap graft (K041528). Both predicate devices use materials with an extensive history of use in cardiovascular and other medical applications and have been thoroughly tested historically for their respective 510(k) clearances. All materials used in the manufacture of the Vascutek Cannula Graft are biocompatible and non-toxic.

The physical properties of the combined predicate devices i.e. the Terumo Soft-Flow® Aortic Cannula (K934127) and the Vascutek SEALPTFE Wrap graft (K041528) remain unchanged and the point of attachment of the component devices has been tested and shown to be suitable for the intended use.

The Vascutek Cannula Graft is a finished product, provided sterile for single use only.

The overall length of the Vascutek Cannula Graft is approximately 50 cm and the cannula and graft portions are both 8 mm in diameter. The Vascutek Cannula Graft is only available in a single model i.e. a CGS2008S.

Intended Use:

The intended use of the Vascutek Cannula Graft is:

"*This device is intended to be used in axillary arterial perfusion during cardiopulmonary bypass procedures. These devices are indicated for up to 6 hours of use*".

This intended use is substantially equivalent to the intended use of the Terumo Soft-Flow® Aortic Cannula predicate device, K934127 i.e. arterial perfusion during cardiopulmonary bypass.

Principles of Operation and Technology:

Cardiopulmonary bypass temporarily takes over the function of the heart and lungs when patients are undergoing surgery. Cardiopulmonary bypass maintains the circulation of blood and the oxygen content of the patient's body. Cardiopulmonary bypass consists of two main functional units, the pump and the oxygenator, which removes oxygen deprived blood from a patient's body and replaces it with oxygen-rich blood through a series of tubes. Arterial cannulae are commonly used to enable connection of the patient to a cardiopulmonary bypass machine.

Performance:

Studies were undertaken, specifically to address the attachment site of the Terumo Soft-Flow® Cannula (K934127) and the Vascutek SEALPTFE Wrap graft (K041528). Testing consisted of tensile strength and leak testing. Results demonstrated that the strength of the attachment of the two combined devices was greater than the tensile strength of the

predicate Terumo Soft-Flow® Cannula itself (K934127). No leakage was observed demonstrating equivalence to both predicate devices. These results were also demonstrated after 2 years accelerated ageing of the Vascutek Cannula Graft.

Substantial Equivalence:

The Vascutek Cannula Graft is substantially equivalent in intended use, design and materials, performance, principles of operation and technology to the predicate devices, which are summarised below. This is shown comprehensively in Table 2, Section 10 of this pre-market notification.

Intended Use:

Vascutek's Cannula Graft and the Terumo Soft-Flow® Cannula predicate device (K934127) share the same intended use, i.e. both are indicated for arterial perfusion during bypass surgery for up to 6 hours.

The Vascutek Cannula Graft and both predicate devices are intended for prescription use only.

Design and Materials:

The design of the Vascutek Cannula Graft is the same as the predicate devices i.e. it is a combination of a Terumo Soft-Flow® Cannula and a Vascutek SEALPTFE Wrap graft. The only difference is the replacement of the PVC tip of the Terumo Soft-Flow® Cannula (K934127) with a Vascutek SEALPTFE Wrap graft (K041528). As stated previously, the replacement of the cannula tip with a softer, SEALPTFE Wrap vascular graft, maybe less traumatic and be preferred by some surgeons.

The materials of the Vascutek Cannula Graft are the same as the predicate devices i.e. PVC (Terumo Soft-Flow® Cannula) and gelatin sealed ePTFE (Vascutek SEALPTFE Wrap graft).

There are therefore no new materials other than the medical grade adhesive used at the point of attachment, which has undergone comprehensive biocompatibility testing, which demonstrates that it is biocompatible and non-toxic.

Performance:

Studies on the performance of the attachment site demonstrated that the strength of the attachment of the two combined devices was greater than the predicate Terumo Soft-Flow® Cannula itself (K934127). No leakage was observed demonstrating equivalence to both predicate devices. These results were also demonstrated after 2 years accelerated ageing of the Vascutek Cannula Graft.

Principles of Operation and Technology:

Both the Vascutek Cannula Graft and the predicate Terumo Soft-Flow® Cannula (K934127) are used in open heart surgery to return oxygenated blood to the patient.

The Vascutek Cannula Graft and both predicate devices are intended only for use in hospital operating theatres by suitably qualified surgeons.

The Vascutek Cannula Graft and both predicate devices are provided sterile by ethylene oxide for single use only.

Addition Information:

Vascutek Cannula Grafts are packaged using the same materials as those used for Vascuteks other vascular graft products and the Vascutek SEALPTFE Wrap graft predicate device (K041528).

Vascutek has conducted testing on aged and non-aged Vascutek Cannula Grafts to demonstrate stability of the materials and found the Vascutek Cannula Graft to be stable over the expiry of the product i.e. 2 years.

Substantial Equivalence Summary:

In summary, the Vascutek Cannula Graft is substantially equivalent in intended use, design and materials, performance, principles of operation and technology to the predicate devices

Conclusion:
In conclusion, the Vascutek Cannula Graft is substantially equivalent to the predicate devices in commercial distribution and results of non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate devices.

.....Karen Cobb.....
Signature

.....10-2-09.....
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 2009

Vascutek Ltd.
c/o Ms. Karen Kelso
Regulatory Affairs Manager
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Renfrewshire, Scotland
PA4 9RR, United Kingdom

Re: K081560
Vascutek Cannula Graft
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing Vascular, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DWF
Dated: January 19, 2009
Received: January 22, 2009

Dear Ms. Kelso:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081560

Device Name: Vascutek Cannula Graft

Indications for Use: This device is intended to be used in axillary arterial perfusion during cardiopulmonary bypass procedures. These devices are indicated for up to 6 hours of use.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K081560

(Posted November 13, 2003)